Interactive CD-ROM for Coping with Breast Cancer

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Abbreviated Abstract

A diagnosis of breast cancer is frequently and understandably associated with high levels of psychosocial distress. While support groups and stress-management interventions have: (a) increased social support, (b) reduced psychosocial and physiological stress, (c) improved active coping, and (d) enhanced psychosocial adjustment, the literature indicates that less than 10% of patients attend these group-based interventions. In the Phase I project we developed an innovative interactive multimedia instructional stress-management program on CD-ROM entitled, "Living With Breast Cancer" (LWBC). This product is unique in that it (a) describes and normalizes the range of emotional reactions women with breast cancer experience, (b) organizes and walks women through the medical landscape of breast cancer, (c) directs women's education queries to appropriate sources when they need them, (d) offers skill building strategies for alleviating psychosocial stress and for creating and maintaining constructive social support, and (e) is accessible and conveniently used by women who are otherwise unable or disinclined to participate in support groups.

The goals of the Phase II project are to: (a) enhance and further refine our product for use by women with breast cancer, and (b) complete the product evaluation in a randomized controlled trial to determine the effects of the product. One hundred (100) women at the Alta Bates site will be randomly assigned either to the Enhanced Usual Care group (EUC) who will receive an educational breast cancer video presentation, or to the CD-ROM Intervention group (CDI) who will receive the LWBC interactive stress management product in addition to the educational video. Assessments will occur at baseline and at a 3 month follow-up, and will obtain data on: (a) psychosocial stress (perceived stress); (b) psychosocial distress (i.e., depression, trauma symptoms); coping and social support; (c) breast cancer disease outcomes (i.e., recurrence); and (d) consumer satisfaction. In addition, two additional studies will be completed. The first, a pilot product evaluation study includes 10 diagnosed women who will not be included in the randomized trial, but will provide data for analyzing the longer range (5-10 months) outcomes associated with and the use of the LWBC program. The second additional study will provide detailed qualitative data gathered using the Life Events and Difficulties Schedule (LEDS) with 30 women. Interview data provide comprehensive information on acute and chronic stressful life events occurring one year prior to diagnosis and during treatment and recovery. These data will provide useful information on the degree to which chronic and acute life stressors relate to perceived stress and health status.

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Total Budget

$977,888

Research Objectives

AIMS

1) Evaluate chronic and acute life stressors in relation to perceived stress and cancer health status.
2) Use a controlled randomized design to measure changes in perceived stress and cancer health status. Compare usual care cancer treatment to the addition of the Living with Breast Cancer (LWBC) interactive multimedia stress management instructional program.
3) Evaluate users' satisfaction with the LWBC program in relation to ease of use and perceived benefits.
4) Produce an upgraded, commercially marketable LWBC program based on research findings.

Theory/Hypothesis

Evidence supports the conclusion that participation in support groups for women with breast cancer can help improve outcomes on a variety of psychosocial measures. However, only 10% of women participate in support groups. Our project tests the hypothesis that in response to a breast cancer diagnosis, a computer-based interactive multimedia program ("Living with Breast Cancer" or LWBC) that provides individualized, self-paced instruction on coping with stress will provide benefits greater than usual cancer care.

Experimental Design

The primary experimental design will be a controlled randomized comparison of (a) a control group that receives "usual care" following diagnosis of breast cancer, with (b) a randomly assigned experimental group that receives equivalent "usual care" plus the LWBC Program. Two additional studies will also be included: (a) a pilot study that

provides pre-post information on changes in perceived stress, emotional distress and cancer health status before and after use of the LWBC program; and (b) a qualitative study of acute and chronic life stressors in relation to the same outcomes.

Final Sample Size & Study Demographics

Participants in the clinical trial will be 110 women with biopsy-proven invasive breast cancer, of any stage, who are enrolled in the study within 6 months of diagnosis and are undergoing treatment at either the Willamette Valley Cancer Center (WVCC) in Oregon (n=10) or the Alta Bates Cancer Care Center (ABCCC) in California (n=100). Women must be over 18 years of age, able to give informed consent, speak and read English, have no other cancer or life-threatening illness or other condition that would prevent them from participating in assessments, and must have no plans to move from the area for the duration of the study.

Data Collection Methods

The Life Event Difficulty Schedule (LEDS) will be administered to 30 participants, including all 10 from Oregon, plus 20 of the 100 participants from California who complete the LEDS face-to-face interviews. The LEDS assessment involves a semi-structured interview format about events occurring within a specified time frame (in this case one year preceding diagnosis). These data will be collected three months prior to distribution of the LWBC program. An exception to this involves the 10 Oregon participants. Many of this sample were involved in testing the product during development. They enrolled within six months of diagnosis and completed the LEDS interviews, but received the product at varying times during the development phase and received the product as versions were created. (Since they did not receive the product at precisely the 3-month interval, these participants are not included in the randomized controlled product evaluation study.) Brief follow-up LEDS interviews will be administered at approximately 3 and 6 months (with some variability) after dissemination of the LWBC program.

All 110 participants will also complete a baseline assessment that includes a selection (see below) of questionnaires developed to measure perceived stress, emotional distress, coping strategies and social support. Basic demographic information will be obtained at baseline, as will basic health status indicators. All of these measures will be obtained again at a three-month follow-up interval following dissemination of the LWBC program. Record reviews will be done at baseline and at follow-ups to verify medical information. The 30 participants in the qualitative study, described above, will also be assessed with the same measures at approximately 6 months after dissemination of the program. All 110 participants will also complete a questionnaire after completion of the study providing data on user satisfaction with the program.

Outcome Measures

Life Event Difficulty Schedule (LEDS). LEDS assessment involves several steps. The interviewer begins by collecting basic biographic information, learning about the life context of the participant, and building rapport. Participants are then encouraged to describe stressful life events, both acute and chronic, in detail. The information is presented to one or more raters who are blind to the dependent variable. Manuals detailing specific criteria in each event category guide the raters in deciding whether a given incident meets criteria for an event (acute stressor) or a difficulty (chronic stressor). Events and difficulties meeting criteria are then scored on a number of scales using a standardized LEDS procedure.

Social support. The UCLA Social Support Inventory (Schwarzer, Dunkel-Schetter, & Kemeny, 1994) is a 24-item measure of social support designed to tap into several aspects of social support. Developed on samples of breast cancer patients, it yields scales for sources of support, support dimensions, negative support, and how participants ask for support.

Perceived stress. The Perceived Stress Scale (PSS; Cohen, Karmack, & Mermelstein, 1983) is a 14-item measure based on the transactional stress theory of Lazarus. This measure has been found to be an independent and significant predictor of physical symptoms and health behaviors after controlling for psychological symptoms (Cohen et al., 1983).

Depression. Depressive symptomatology will be assessed using the Center for Epidemiological Studies–Depression (CES-D) scale, a 20-item self-report inventory assessing the frequency of depression symptoms occurring during the past week on a four-point scale (CES-D; Radloff, 1977).

Trauma. A self-report measure of PTSD, the Post-Traumatic Stress Disorder Checklist- Symptom Version (PCL-S), will also be used. The PCL was developed to assess PTSD symptoms in relation to a designated trauma (e.g., having breast cancer) for a clinical diagnosis under DSM-IV (Blake et al., 1990; Blanchard, Jones-Alexander, Buckley, & Forneris, 1996). The total score is used to assess total level of anxiety, with a cut off score indicating a DSM-IV diagnosis of PTSD.

Coping. The Mental Adjustment to Cancer Scale (MAC; Greer, Stirling, & Watson, 1989) was designed to measure patients' strategies for handling their cancer diagnosis and treatment. It yields five subscales: Fighting Spirit (I am determined to beat this disease), Anxious Preoccupation (I am apprehensive), Helpless/Hopeless ("I feel like giving up"), Fatalism ("I've had a good life, what's left is a bonus"), and Denial/Avoidance ("Not thinking about it helps me cope"). The current version is the MINI MAC scale, which was developed to improve upon the reliability of the MAC (Watson, Law, dos Santos, & Greer, 1994).

Consumer Use and Opinion Survey. A questionnaire assessing product use and evaluation will be given to the treatment group at the end of each follow-up assessment to solicit qualitative feedback regarding the relevance of the program, clarity of the instructions, and ways to make the program more enjoyable or better. In addition, quantitative information will be collected regarding (a) the amount of program use, (b) number and type of coping and support strategies used prior to the use of the product and after use of the product, and (c) perceived impact the program had on the ways women coped with breast cancer. Finally, a 12-item instrument using a 6-point Likert-type scale (from "strongly disagree" to "strongly agree') will be administered to ascertain information on ease of use, effectiveness of the instructions, usefulness of each module, and likelihood of recommending the product to another woman with breast cancer.

Evaluation Methods

Our analyses fall into two main groups: those with numeric outcomes (e.g., symptom severity level), and those with categorical outcomes (e.g., onset of depression/no onset of depression). Numeric outcome measures will be analyzed with random regression models. We will supplement these relatively new techniques with more conventional general linear models (e.g., ANCOVA, univariate and multivariate repeated measures ANOVA, multiple regression).

Categorical outcome data will be analyzed with contingency table analysis (chi-square tests, odds ratios) including multi-dimensional and longitudinal tables, and logistic regression analysis. In addition, we will use statistical procedures that have become recently available (MIXOR) for testing random-effects probit regression models. Finally, survival analyses (life tables, Cox regression models) will be employed where appropriate (e.g., examining time to relapse).

Preliminary analyses will be conducted in order to determine whether any biases resulted from the random assignment or from subject attrition; demographic, medical history, psychosocial functioning, and physiological measures with significant differences will be included as covariates in subsequent analyses. Other potential confounding variables, such as any other treatment received during the study (e.g., medications), will be examined and, if needed, will be included as covariates. Using random regression modeling, we will compare the improvement rate (i.e., slope) for the two intervention conditions using the questionnaire data (measured at baseline, 3-month follow-up) such as the CES-D as well as using the interview data (measured at baseline, 3- and 6-month) such as the LEDS. For replication and validation, these analyses will be repeated for each of the numeric measures of depression and psychosocial functioning. In addition to the random regression modeling**,** an ANCOVA approach will be used to determine if significantly differential rates of the continuous outcome measures are observed at specific time points after controlling for the reported rates at the baseline assessment. Minority status differences are of considerable interest; minority status will be included in both the random coefficient and ANCOVA analyses.

Research Results

Data collection still in process

Barriers & Solutions

Unforeseen circumstances have resulted in delays, requiring the need to streamline the project procedures. Production of the program proved more complex than anticipated, and illnesses and personnel changes have created further barriers to progress. However, we have met these challenges by making several accommodations:

1) A planned companion website will not be developed. This decision was reinforced by the growing availability of web sites offered by other organizations that fulfill the purposes we had originally envisioned for our project.
2) In order to create significant time and financial efficiencies, we have simplified our data collection procedures. This additionally allows us to comply with one of our significant original proposal critiques, which cited the high time and effort burden placed upon our research participants. These changes, listed below, will allow the project to be completed satisfactorily within our current timeline and budget:
   - Cortisol sampling, a physiological measure of stress, will not be utilized as an outcome measure.
   - We will not conduct the Structured Clinical Interview FOR DSM-IV (SCID) (mental health assessment) on any participants.
   - LEDS interviews will be completed on currently enrolled participants, but will not be conducted with participants recruited after September 17, 2008. The LEDS procedure is extremely time-consuming, and by limiting the number of women who participate in the interviews, we will significantly decrease the burden of participation.
   - A shorter, simplified version of the Demographic Questionnaire has been created and will be used in place of the originally planned LEDS Demographic Questionnaire.
   - We will reduce our sample size by approximately 10 clients (110 instead of 120).

Product(s) Developed from This Research

Living with Breast Cancer